

4179-126

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Section III (Remarks)A Summary of Amendments

The second full paragraph of the specification on page 8, starting with “[a]s illustrated, the centrifuge tube 10 ...” has been amended to recite that the body 12 has a substantially uniform diameter along the open proximal end 20, and to recite that relative to a central longitudinal axis extending through the closed distal end 14 and the open proximal end 20, the open proximal end 20 has a cross-sectional area (in a direction perpendicular to the central axis) at least as large as the average cross-sectional area of the centrifuge tube 10. Support for such amendatory language is provided, for example, in Figures 1-10. As noted by the predecessor court to the Federal Circuit, whatever is disclosed by the drawings “may be added to the specification in words without violation of the statute and rule [35 U.S.C. 132, Rule 118] which prohibit new matter.” *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537, 542 (C.C.P.A. 1962). No new matter within the meaning of 35 U.S.C. 132 has been introduced by the present amendment.

B. Response to Restriction Requirement

Claims 30, 39, and 40-42 have been withdrawn, but without relinquishment of the right to request rejoinder of any or all of those claims under the applicable rejoinder provisions of MPEP 821.04 upon confirmation of allowable subject matter in the remaining claims.

C. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 22-29 and 31-38 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The rejection alleged that the claims contained such a matter which was not described in the specification in such a way as to recently convey to one

4179-126

skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the examiner stated:

“Nothing in the present specification describes a body that has a substantially uniform diameter along the open proximal end. Also nothing is set forth regarding the centrifuge tube of body (sic) with an average cross-sectional area in a direction perpendicular to the central axis, and the open proximal has a cross-sectional area at least as large as the average cross-sectional area.”

Applicant respectfully disagrees with any suggestion that the application lacked disclosure of such features, which are shown, for example, in Figures 1-10. Furthermore, Applicant objects to the Examiner's improper statement of a pronouncement of law by the Board of Patent Appeals and Interferences WITHOUT any case citation whatsoever (March 23, 2006 Office Action, page 3, third paragraph). Given the lack of case citation in the Office Action, Applicant is unable to analyze or fairly respond to the Examiner's characterization of legal principles articulated by the BPAI.¹

In response to the rejection under 35 U.S.C. 112, first paragraph, the written description has been conformed to the Figures through the foregoing amendment of the second full paragraph on page 8 of the specification. In view of such amendment, withdrawal of the rejections under 35 U.S.C. 112, first paragraph is respectfully requested.

D. Rejections Under 35 U.S.C. § 103

The March 23, 2006 Office Action contained various claim rejections under 35 U.S.C. § 103, as summarized below:

- Claims 22-24, 26-29, 31-33, and 35-38 were rejected under 35 U.S.C. § 103 as unpatentable for obviousness over U.S. Patent No. 5,255,808 to Tobler (“Tobler”);

¹ Applicant suspects that the purported case to which the Examiner alludes is an unpublished decision that is not binding precedent.

4179-126

and

- Claims 25 and 34 were rejected under 35 U.S.C. § 103 as unpatentable for obviousness over Tobler in view of U.S. Patent No. 3,537,498 to Amand ("Amand").

The above-mentioned claim rejections under 35 U.S.C. 103 are traversed for the reasons provided below.

I. Law Regarding Obviousness

Concerning §103 obviousness rejections, three requirements must be met for a *prima facie* case of obviousness. First, **the prior art reference(s) must teach all of the limitations of the claims.** MPEP § 2143.03. Second, **there must be a motivation to modify the reference or combine the teachings to produce the claimed invention.** MPEP § 2143.01. Third, a reasonable expectation of success is required. MPEP § 2143.02. In addition, the teaching or suggestion to combine and the expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP § 2143.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A further consideration, which applies to all obviousness rejections, is that "[a] **prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.**" *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)." (emphasis in original; MPEP 2141.02).

2. Patentable Distinctions of Claims 22-24, 26-29, 31-33, and 35-38 Over Tobler

Claims 22-24, 26-29, 31-33, and 35-38 include two independent claims – namely, claims 22 and 31 – as recited below:

22. A centrifuge tube having a body with a closed distal end, an open proximal end, and integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, wherein the body has a substantially uniform diameter along the open proximal end.

31. A centrifuge tube having a body with a closed distal end, an open proximal end, and integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, wherein the body has a central axis extending through the closed distal end and the open proximal end, the body has an average cross-sectional area in a direction perpendicular to the central axis, and the open proximal end has a cross-sectional area at least as large as the average cross-sectional area.

Thus, claim 22 requires that the body have “a substantially uniform diameter along the open proximal end,” and claim 31 requires that the “open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area.” Both of these features directly relate to the primary function of the centrifuge tube – namely, to serve as a container for collection and separation of samples. As noted at page 1 of the application:

[C]entrifugation processing produces supernatant and pelleted solids, that are amenable to separation, e.g., by decanting of the supernatant liquid from the solids mass in the lower end of the centrifuge tube.

Centrifuge tubes according to various embodiments of the invention include flexural hinges on opposing sides that permit such tubes to be pressed to a flat conformation at the region of local manual deformation. See Application, page 6. As a result of such construction, a specimen-

4179-126

containing swab may be inserted into the centrifuge tube to a point where the user can grasp opposing side surfaces intermediate the opposing side seams and compress the respective sides to define a narrowed slot opening through which the swab element can be drawn to exude or squeeze liquid-borne specimen out of the swab element for subsequent concentration and analysis by the centrifugation operation. See Application, page 6.

To provide such functionality, centrifuge tubes according to the invention should be adapted to receive a specimen-containing swab and exude liquid-borne sample out of the same, and further adapted for use in a centrifuge for effective concentration and analysis.

Conventional centrifuge tubes typically have a substantially cylindrical form, with or without a conical or other narrowed tip to aid in precipitate compaction. Additionally, many centrifuge tubes typically have a diameter of about one inch or less to permit their use with widely available centrifuges of conventional size, and to avoid the need for excessive amounts of wash or elution liquid.

The requirement of claim 22 that the body have “a substantially uniform diameter along the open proximal end” permits the open proximal end to be sufficiently large to receive a specimen-containing swab element without requiring an unnecessarily large and unwieldy tube that may not be suitable for convenient for centrifugation.

Similarly, the requirement of claim 31 that “the open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area” ensures that the open proximal end is sufficiently large to receive a specimen-containing swab element without

4179-126

requiring an unnecessarily large and unwieldy tube that may not be convenient for centrifugation, while recognizing that the body may have a non-uniform cross-sectional area along its length.

Mistakenly ignoring all of the foregoing reasons why Applicant's recitation in the claims of a "substantially uniform diameter along the open proximal end" and "the open cross-sectional end [have] a cross sectional area at least as large as the average cross-sectional area" enhanced functionality of the claimed devices, the Examiner opined that:

"[t]he particular shape of the body proximal end, uniform, non-uniform, or a cross section at least as large as the average cross section fails to solve any stated problem or is for any particular purpose. In fact nowhere in the present disclosure does applicant explicitly set forth a uniform diameter along the open proximal end. Accordingly, it would have been obvious and well within the level of ordinary skill in the art to construct the distal end uniform, for the reason that such a change would have merely been a matter of design choice."

March-23, 2006 Office Action, page 4. Contrary to such opinion, the reasons for claiming the recited features have been plainly described. Moreover, the amended disclosure does recite a substantially uniform diameter along the open proximal end at the second fully paragraph on page 8.

Against this backdrop, the Examiner opined that claims 22-24, 26-29, 31-33, and 35-38 were obvious over Tobler.

Tobler is not directed to "centrifuge tubes" of any variety – let alone centrifuge tubes embodying the features of the pending claims. Instead, Tobler is directed to foldable bottles (of various shapes including rectangular, essentially round, rectangular/oval, and square/round transverse cross-sections) "distinguished by good stability in the full and empty state as [they have] a large standing surface" (Tobler, col. 2, lines 3-6). Each bottle has a sloping "upper top surface" 4,

4179-126

104, 204, 304 with a reduced diameter “pouring part” 5, 105, 205, 305 arranged therein. **Tobler thus teaches that the base should be large so as to provide stability, with a sloping upper surface leading to a narrowed mouth to facilitate pouring of liquid from the bottle.** Such features of bottles according to Tobler are **CONTRARY** to the “substantially uniform diameter along the open proximal end” limitation of claim 22, and to “the open cross-sectional end [having] a cross sectional area at least as large as the average cross-sectional area” limitation of claim 31. Furthermore, Tobler specifically teaches the presence of a “large standing surface,” making a bottle according to Tobler ill-suited for use with a centrifuge typically having a small aperture size for receiving a centrifuge tube.

The rejection under 35 U.S.C. § 103 of claims 22-24, 26-29, 31-33, and 35-38 is **contrary to law** and therefore untenable in multiple respects.

First, Tobler fails to teach all of the limitations of the claims, as required by MPEP § 2143.03 to support a *prima facie* case of obviousness. Elements recited in the claims and wholly absent from Tobler include: centrifuge tube, substantially uniform diameter along the open proximal end (claims 22 et seq.), and open proximal end having a cross-sectional area as least as large as the average cross-sectional area [of the body] (claims 31 et seq.)). Given Tobler’s failure to teach all of the limitations of the claims, no *prima facie* case of obviousness exists as to claims 22 or 31 (or any claims depending therefrom).

Second, there exists no motivation to modify Tobler to produce the claimed invention, as required by MPEP § 2143.01 to support a *prima facie* case of obviousness. The examiner’s conjured statement that “it would have been obvious and well within the level of ordinary skill in

4179-126

the art to construct the distal end uniform, for the reason that such a change would have merely been a matter of design choice” **lacks any factual basis or support whatsoever** – consistent with the glaring *absence* of any citation to any portion of Tobler. It has been well-established by the Federal Circuit that the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Since the examiner has not identified any particular suggestion in the prior art that Tobler should be modified to yield the claimed invention, no *prima facie* case of obviousness exists as to claims 22 or 31 (or any claims depending therefrom).

Third, the examiner has failed to consider Tobler in its entirety – i.e., including portions that clearly *lead away* from the claimed invention. It is clear from binding Federal Circuit precedent that failure to consider references in their entirety in fashioning obviousness rejections is improper. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *see also* MPEP 2141.02. Applicants have already demonstrated herein that Tobler teaches foldable bottles “distinguished by good stability in the full and empty state as [they have] a large standing surface” (Tobler, col. 2, lines 3-6), such that each bottle has a sloping “upper top surface” 4, 104, 204, 304 with a reduced diameter “pouring part” 5, 105, 205, 305 arranged therein. **Tobler thus teaches that the base should be large so as to provide stability, with a sloping upper surface leading to a narrowed mouth to facilitate pouring of liquid from the bottle.** Such features directly contradict the “substantially uniform diameter along the open proximal end” limitation of claim 22, and to “the open cross-sectional end [having] a cross sectional area at least as large as the average cross-sectional area” limitation of claim 31. Furthermore, Tobler specifically teaches the presence of a “large standing surface,” making a bottle according to Tobler ill-suited for use with

4179-126

a centrifuge typically having a small aperture size for receiving a centrifuge tube. **Thus, there exist many teachings in Tobler that contradict the modifications necessary to yield the centrifuge tubes recited in independent claims 22 and 31 (and the claims depending therefrom), and the examiner's failure to consider Tobler in its entirety is facially erroneous.**

In view of the many defects in the rejection under 35 U.S.C. § 103 of claims 22-24, 26-29, 31-33, and 35-38, withdrawal of the rejection of these claims is warranted, and respectfully requested.

3. *Patentable Distinctions of Claims 25 and 34 over Tobler in View of Amand*

Claims 25 and 34 depend from and therefore inherently include all of the limitations of independent claims 22 and 31, respectively. It has already been demonstrated herein that Tobler fails to teach or suggest all of the limitations of claims 22 and 31, and such arguments are hereby incorporated by reference as to claims 25 and 34 as if reiterated in their entirety. **Amand fails to supply the teachings missing in Tobler in this regard.** For at least the reason that any combination of Tobler and Amand fails to teach all of the limitations of claims 25 and 34, withdrawal of the rejection of such claims under 35 USC 103 is respectfully requested.

Yet another reason why claims 25 and 34 are patentably distinct over any combination of Tobler and Amand is that **there exists no motivation to combine the teachings of the two references to produce the claimed subject matter – indeed, Amand teaches away from making such a combination.** The examiner concedes that Tobler fails to disclose any concave depressions, and points to Amand as teaching a concave depression on an exterior surface facing one another. March 23, 2006 Office Action, pages 4-5. Thereafter, the examiner states that “[i]t would have been obvious to one of ordinary skill in the art to modify the containers of the prior art [i.e., Tobler and Amand] by constructing such a feature” with “the motivation for this modification

4179-126

[being to] permit grasping thereof.” *Id.* The proposed combination of Tobler and Amand betrays yet another failure by the examiner to consider prior art references in their entirety (see *W.L. Gore & Associates, Inc. v. Garlock, Inc., supra*) – including portions that lead away from the claimed invention.

Claims 25 and 34 are not merely directed to a bottle having concave depressions; rather, the claims recite, *inter alia*, **centrifuge tubes having integral hinge elements with concave depressions between the hinge elements**, as provided below:

25. The centrifuge tube of claim 22, wherein the body comprises concave depressions on an exterior surface of the tube, oppositely facing one another, between the respective integral hinge elements.

34. The centrifuge tube of claim 31, wherein the body comprises concave depressions on an exterior surface of the tube, oppositely facing one another, between the respective integral hinge elements.

Amand is directed to a generally rectangular plastic bottle for storing and dispensing sterile medical liquids. While the examiner correctly points out that the plastic bottle of Amand does include concave depressions on exterior surfaces facing one another, the examiner omits mention of the fact that such indentions are thickened to permit the container to be manually grasped without changing the internal volume of the bottle. Amand repeatedly refers to the addition need to avoid flexure problems that would cause a bottle’s internal volume to decrease when grasped. Amand, col. 1, lines 11-42. Amand’s teaching to add reinforced wall sections to avoid wall flexure represents a clear teaching away from the use of hinge elements along the outside of a vessel. The present application clearly and repeatedly discusses the desirability of providing a centrifuge tube with integral hinge elements specifically to permit the tube to be pressed to a flat conformation to permit sample to be extracted from a swab element placed into the interior of a bottle. Amand’s reinforced regions specifically intended to prevent flexure cannot be

4179-126

construed in any way to disclose or suggest the use of hinge elements intended to enable flexure – and likewise cannot be used to support or motivate any combination of references to yield a structure having integral hinge elements. Since there exists no motivation to combine Tobler and Amand, no *prima facie* case of obviousness exists as to claims 25 and 34 pursuant to MPEP § 2143.01. Accordingly, withdrawal of the rejection under 35 USC § 103 of these claims is respectfully requested.

E. Consideration of Enclosed Information Disclosure Statement and Declaration Under Rule 1.131

A Supplemental Information Disclosure Statement (IDS) is enclosed herewith for consideration by the Examiner. Payment of the \$180.00 fee accompanying such IDS is authorized in the enclosed Credit Card Payment Form.PTO-2038.

One of the references cited in the enclosed IDS is U.S. Patent Application Publication No. 2004/0267181 to Tuite, et al. ("Tuite"), which discloses (e.g., at Figs. 2a-2b) a centrifuge tube having integral "spine" or hinge elements. Further enclosed herewith is a Declaration by inventor Tilak M. Shah under 37 CFR §1.131, attesting to the fact that the instant claimed invention, as recited in pending claims 22-29 and 31-39, was made prior to the effective date of Tuite. By such Declaration, Tuite is removed as a potential prior art reference.

CONCLUSION

Claims 22-29 and 31-39 have been fully distinguished over the cited references, and are in form and condition for allowance. Issuance of a Notice of Allowance for the application is therefore requested. If any issues remain outstanding, incident to the formal allowance of the application,

4179-126

the Examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss the same, in order that this application may be allowed and passed to issue.

Respectfully submitted,



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Enclosures:

Credit Card Payment Form PTO-2038 authorizing \$405.00 [1 pg]

Supplemental Information Disclosure Statement and Completed Form PTO/SB/08a [3 pgs]

Declaration of Tilak M. Shah Under 37 C.F.R. § 1.131 and Exhibit [7 pgs]

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